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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/551,734	10/03/2005	Roland Callens	05129-00103-US	4319
23416 7590 07/17/2008 CONNOLLY BOVE LODGE & HUTZ, LLP P O BOX 2207 WILMINGTON, DE 19899				
EXAMINER YOUNG, SHAWQUITA				
ART UNIT 1626		PAPER NUMBER		
MAIL DATE 07/17/2008		DELIVERY MODE PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/551,734

**Applicant(s)**

CALLENS ET AL.

**Examiner**

SHAWQUA YOUNG

**Art Unit**

1626

**Period for Reply** -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 June 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-18 and 20-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 and 20-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 1-18 and 20-35 are currently pending in the instant application. The Examiner is withdrawing the finality of the last Office Action because of present 112, 1<sup>st</sup> issues that have not been discussed previously. Prosecution of the case has been reopened.

#### **I. *Response to Arguments/Remarks***

Applicants' amendment, filed on June 11, 2008, has overcome the rejection of claims 20-35 under 35 USC 112, first paragraph as failing to comply with the written description requirement for the term "amino acid derivatives"; the rejection of claims 20-35 under 35 USC 112, second paragraph as being indefinite and the objection of claim 19 as being dependent upon a rejected claim. The above rejections have been withdrawn.

#### **II. *Rejection(s)***

Claims 1-18 and 20-35 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for preparing several amino acid derivatives (See pages 5-13 of the specification), does not reasonably provide enablement for preparing all amino acid derivatives selected from listed in claim 1 such as 2-piperidineacetic acid. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

As stated in the MPEP 2164.01 (a), "There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue."

In In re Wands, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have need described. They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.

In the instant case

***The nature of the invention***

The nature of the invention is a process of preparing amino acid derivatives wherein the amino acid derivatives are selected from the group consisting of  $\beta$ -homovaline,  $\beta$ -homophenylalanine,  $\epsilon$ -trifluoroacetyl- $\beta$ -homolysine,  $\beta$ -homolysine,  $\beta$ -homoaspartic acid,  $\beta$ -homoproline, pyrrolidine-2-acetic acid and 2-piperidineacetic acid.

***The amount of direction or guidance present and the presence or absence of working examples***

The only direction or guidance present in the specification and the only working examples present in the specification are for producing specific amino

Art Unit: 1626

acid derivatives and the organic amines used as starting materials as described on pages 5-13 of the applicants instant specification. The process for the preparing the various amino acid derivatives listed in claim 1 is not clearly defined in the specification. Applicants have only provided two working examples in the specification but do not provide a genus process for preparing the different amino acid derivatives listed in the claims.

***The breadth of the claims***

The breadth of the claims is a process for producing amino acid derivatives wherein the amino acid derivatives are selected from the group consisting  $\beta$ -homovaline,  $\beta$ -homophenylalanine,  $\epsilon$ -trifluoroacetyl- $\beta$ -homolysine,  $\beta$ -homolysine,  $\beta$ -homoaspartic acid,  $\beta$ -homoproline, pyrrolidine-2-acetic acid and 2-piperidineacetic acid.

***The quantity of experimentation needed and the level of the skill in the art***

While the level of the skill in the pharmaceutical art is high, the quantity of experimentation needed is undue experimentation. One of skill in the art would need to prepare compounds with similar structural radicals without any direction as to what structural radical is needed and how different the derivative can be from any of the amino acids or organic amines.

The level of skill in the art is high without showing or guidance as to how to make these other derivatives it would require undue experimentation to figure out the starting materials, solvents, temperatures and reaction times that would provide other derivatives or organic amines.

Claims 1-18 and 20-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The "carbanionic reagent" in step (b) of the claimed invention is not defined in the specification so as to know the structures of the compounds that are included and/or excluded by the term. Therefore, the specification lacks adequate support for Claims 1-18 and 20-35.

### **III. Conclusion**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shawquia Young whose telephone number is 571-272-9043. The examiner can normally be reached on 7:00 AM-3:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1626

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Shawquia Young/

Examiner, Art Unit 1626

/Kamal A Saeed, Ph.D./

Primary Examiner, Art Unit 1626